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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,023	12/30/2004	Magnus Qvist	66876-78247	5081

26288 7590 07/05/2006

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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,023	QVIST, MAGNUS	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 3, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

DETAILED ACTION

Applicants' election of Invention of Group I, **Claims 1-8 and 10**, in response to the restriction requirement mailed January 3, 2006 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Status of the claims

Claims 1- 10 are pending. **Claim 9** is withdrawn for pertaining to non-elected subject matter. **Claims 1-8 and 10** are presently under examination.

Priority

The current application filed on December 30, 2004 is 371 of PCT/SE03/01088 filed on June 24, 2003, which in turn claims priority to provisional application 60/392971- filed July 2, 2002 and foreign application, SWEDEN 02020659 filed on July 2, 2002. A certified copy of foreign document SWEDEN 02020659 has been provided.

Preliminary Amendment

The preliminary amendment filed December 30, 2004 has been entered.

Information Disclosure Statement

The IDS filed December 30, 2004 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

This application contains sequence disclosures at page 5, lines 8-20 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures". Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** applicants state that the composition of the invention consists of an acidic solution of a bioadhesive polyphenolic protein, wherein the pH of the solution is 4; however it is not clear how the mentioned solution can be acidic since it only consists of the said polyphenolic protein which is not naturally acidic.

In dependent **claims 4-6** the applicants state that the said acidic solution comprises an organic acid, an inorganic acid or citric acid, acetic acid and ascorbic acid but this cannot be possible since the applicants have already limited **claim 1** to consist of only a polyphenolic protein and nothing else. Furthermore, in **claim 1**, there is no mention of the said composition containing an acid, indicating that the said dependent claims also suffer from insufficient antecedent basis

Claims 2-3, 7-9 and 10 are dependent claims that do not remedy the deficiencies of the independent claim that they depend from.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/44401 in view of Burzio United States Patent No. 5,410,023.

WO 01/44401 discloses a composition comprising an aqueous solution of a bioadhesive polyphenolic protein derived from a byssus-forming mussel, which protein comprises 30-300 amino acids and consists essentially of tandemly linked peptide repeats 3-15 amino acid residues, wherein at least 5% of the amino acid residues of said bioadhesive polyphenolic protein are DOPA (page 4, lines 15-29) that can be used for attaching two surfaces or coating a surface. In examples 1-13, pages 7-17, it is

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demonstrated and discussed how the composition of the invention is used in a method of attaching two surfaces or coating a surface. For example on page 8, lines 4-11 of WO 01/44401, it is stated that a block of corneal tissue was thereby isolated and removed from the original site and mussel adhesive protein (MAP) was administered into the wound cavity and thereafter where the shortly before removed corneal tissue pieces repositioned into the cavity to test for the adhesion and reattachment mediated by the MAP glue.

WO 01/44401 teaches that the useful concentration of the mentioned polyphenolic protein is in the range of 0.1-50 mg/ml (Page 6, lines 29-32).

WO 01/44401 also teaches that at least one of the surfaces to be attached or the surface to be coated is a biological surface (Page 8, lines 5-11)

WO 01/44401 does not teach that the bioadhesive composition is an acidic solution wherein the pH of the said acidic solution is 3 or less, wherein the acid solution comprises acetic acid.

Burzio teaches a polyphenolic solution, wherein the pH is at about 3 and wherein the acidic pH is achieved by using acetic acid (column 3, lines 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain a bioadhesive composition comprising a polyphenolic protein containing DOPA for the advantages of a stable solution that can be sufficiently maintained until it is needed for use, as taught by WO 01/44401 and Burzio, see Burzio at column 3, lines 1-9.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Patent Examiner
Group 1653

Robert B. Mondesi
E-21-06

Notice to Comply	Application No.	Applicant(s)	
	10/520,023	QVIST, MAGNUS	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Amino acid sequences not designated by a SEQ ID NO.; see page 5, lines 18-20.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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